MAY 2 2 2002

K013846

SMDA REQUIREMENTS
510(k)
SUMMARY OF SAFETY AND EFFECTIVENESS FOR THE UltraGard™ IMPERVIOUS REINFORCED GOWN

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

Submitter's Name: Precept Medical Products, Inc.
370 Airport Road
Arden, North Carolina 28704 USA
Telephone: (828) 681-0209

Contact Person: Mary Ann Faulkner, V. P. Quality Assurance/Regulatory Affairs

Date of Summary: April 19, 2002

Device Name: UltraGard™ Blue Operating Room Gown with Impervious Reinforced Chest and Sleeves.

Device Classification: The legally marketed device has been classified as follows: Surgical gown drape and drape accessories; (79 FPH); 21 CFR § 878.4040.

Legally Marketed Devices To Which Equivalence Is Claimed: The legally marketed predicate device is the Kimberly-Clark ULTRA Zoned-Impervious Gown (K842115), determined to be substantially equivalent to a legally marketed device on June 11, 1984. The UltraGard™ Blue O. R. Gown with Impervious Reinforced Chest and Sleeves is substantially equivalent to the Kimberly-Clark ULTRA Zoned-Impervious Gown in the intended use and in the performance attributes.

Device Description: The UltraGard™ Blue O. R. Gown with Impervious Reinforced Chest and Sleeves is composed of a single base layer of SMS non-woven material with reinforced areas of the chest and sleeves. The reinforced area contains an additional layer of polyester laminated to a film.

Intended Use: The UltraGard™ Blue O. R. Gown with Impervious Reinforced Chest and Sleeves is a sterile, single use, disposable garment to be used during surgical procedures in the operating room to help protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material.

Descriptive Summary Of Technological Characteristics And Those Of Predicate Device: The UltraGard™ Blue O. R. Gown with Impervious Reinforced Chest and Sleeves is made of a composite of multiple layers of nonwoven material similar to the Kimberly-Clark ULTRA Zoned-Impervious Gown.

Performance Data: The material used in the manufacture of the UltraGard™ Blue O. R. Gown with Impervious Reinforced Chest and Sleeves was tested in accordance with applicable standards and was determined to pass the Resistance of Materials Used in Protective Clothing to Penetration by Synthetic Blood ASTM F1670-98 and the Viral Penetration testing, ASTM

F1671-97b in the reinforced gown areas. The material was tested in accordance with the National Fire Protection Association No. 702-1980, "Wearing Apparel Flammability" and meets Class 1. These devices meet the requirements for biocompatibility per ISO 10993 for surface devices, intact skin, limited duration (< 24 hours). These materials also were tested in accordance with applicable industry recognized test methods and were found to be acceptable for the intended use.

Gown Pack Information: Each gown is packaged with a towel. The towel is the same towel that is currently placed in our gown packs. This towel has been used safely and effectively for many years as a component of the gown pack.

Conclusion: The information and data provided in this 510(k) Notification establish that the UltraGard™ Blue O. R. Gown with Impervious Reinforced Chest and Sleeves is substantially equivalent to a legally marketed device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 22 2002

Ms. Mary Ann Faulkner
Vice President, QA/RA
Precept Medical Products, Incorporated
370 Airport Road
Arden, North Carolina 28704

Re: K013846
Trade/Device Name: Ultragard™ Blue Operating Room Gown with Impervious Reinforced Chest and Sleeves
Regulation Number: 878.4040
Regulation Name: Surgical Gown
Regulatory Class: II
Product Code: FYA
Dated: April 19, 2002
Received: April 23, 2002

Dear Ms. Faulkner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements

of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

April 19, 2001

510(k) Number: K013846

Device Name: UltraGard™ Blue O. R. Gown with Impervious Reinforced Chest and Sleeves.

Indications for Use: UltraGard™ Blue O. R. Gown with Impervious Reinforced Chest and Sleeves is indicated for use in operating room procedures as a sterile cover garment.

(Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-the-Counter Use_____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K013846